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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/001,596 | 10/19/2001 | Mohammad Thudor | 1171/39672/106 | 3006 |

7590 08/31/2004

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| EXAMINER | |
|---|---|
| PAIK, SANG YEOP | |
| **ART UNIT** | **PAPER NUMBER** |
| 3742 | |

DATE MAILED: 08/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/001,596 | THUDOR ET AL. | |
| | Examiner | Art Unit | |
| | Sang Y Paik | 3742 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *25 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-17 and 19-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 19-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 2, 15-17, 19, 20, 33 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gradon et al (US 6,349,722).

Gradon et al discloses the breathing assistance apparatus claimed having a humidifier (10) with a water heater plate (9) for humidifying the gas, a conduit with a conduit heater (15), a flow rate sensor, a temperature sensor (18) via which the water heater is controlled, a controller (11) having programs to determine and adjust various parameters such as temperature, gas flow, humidity level that relate to the gas flow and to determine the electrical power level necessary to produce the desired humidity and temperature in the gas flow. Gradon et al further shows that the controller continuously and repeated monitors the humidification parameter threshold values to produce the desired threshold values.

However, Gradon et al does not show the controller is programmed to monitor input power supplied to the conduit heater to provide an indication of the resistance or temperature of the conduit heater.

Gradon et al shows the controller having the memory that determines the power necessary to generate the humidity level for the heater plate. Gradon et al further shows that the controller is also manipulated to control the heater plate as well as the conduit heater to provide

the required humidity and temperature of the gas flow. While Gardon et al does not explicitly show that a memory is provided for the conduit heater to determine the power necessary to generate the humidity and temperature of the gas flow in the conduit, it would have been obvious to provide the controller with the required power level for the conduit heater as is done with the heater plate to determine the input power that is required to produce the desired humidity and temperature level in the conduit heater. The temperature generated by the conduit heater to prevent condensation in the conduit is an indication of the temperature of the conduit heater. Furthermore, it would have been obvious to one of ordinary skill in the art to continuously monitor the changes in the parameters of the gas flow in the conduit to further implement the controller to achieve the desired parameter values.

With respect to claim 17, while the parameter defined as the power drawn by the water heater divided by the temperature of the water heater is not shown, because such parameter is proportionally related to the power and temperature of the water heater, and it would have been obvious to one of ordinary skill in the art to use any suitable parameters such as the ratio of the power divided by the temperature or vice versa for the convenience of calculation by the controller to produce the desired humidification.

3. Claims 3-5, 10, 21-28, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gradon et al as applied to claims 1, 2, 15-17, 19, 20, 33 and 36 above, and further in view of Daniell et al (US 5,558,084).

Gradon et al shows the breathing assistance apparatus claimed except an ambient temperature sensor.

Daniell et al '084 shows a breathing apparatus having an ambient temperature sensor to sense and to indicate the exterior ambient temperature so as to further adjust a heating element in accordance to the ambient temperature sensor to prevent the condensation of the humidified gases. In view of Daniell et al '084, it would have been obvious to one of ordinary skill in the art to adapt Gradon et al with an exterior ambient sensor to measure the exterior temperature to further determine and supply the power level required to produce the desired gas flow.

With respect to claim 4, Gradon et al further shows the change of the temperature with respect to time to adjust the desired temperature level (see column 18, lines 20-51). With respect to claims 5 and 23, it would have been obvious to one of ordinary skill in the art to adapt Gradon et al, which shows the flow sensor and the controller which controls and adjusts the flow in response to the flow sensor, to further determine the conditions of the conduit heater to prevent condensation in the conduit so that the desired humidity level can be maintained.

With respect to claim 26, it is well known in the art that power is the product of voltage and current, and the temperature and resistance is affected by the voltage or current signal since the temperature and resistance is proportionally related to the amount of power, which comprises voltage and current, applied to the conduit heater.

4. Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gradon et al as applied to claims 1, 2, 15-17, 19, 20, 33 and 36 above, and further in view of Orosy et al (US 3,789,190).

Gradon et al shows the breathing assistance apparatus claimed except estimating the temperature of the conduit heater based on the resistance of the conduit heater.

Orosy et al shows an electrical resistive heating element whose electric resistance is used to measure the temperature of the heater. In view of Orosy et al, it would have been obvious to one of ordinary skill in the art to adapt Gradon et al with the electric resistance measurement as the basis for determining the temperature of the heater in combination with other factors such as the humidity or gas flow rate that affects the temperature of the conduit heater.

With respect to claim 8, it is well known in the art that power is the product of voltage and current, and the temperature and resistance is affected by the voltage or current signal since the temperature and resistance is proportionally related to the amount of power, which comprises voltage and current, applied to the conduit heater.

5. Claims 11-14 and 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gradon et al as applied to claims 1, 2, 15-17, 19, 20, 33 and 36 above, and further in view of Daniell et al (US 6,050,260).

Gradon et al shows the apparatus claimed except supplying the humidifier at a required pressure and flow rate.

Daniell et al '260 shows supplying gas at a required pressure and rate by the means of blower and pressure regulating speed fan with the control means to control the desired rate. In view of Daniell et al, it would have been obvious to one of ordinary skill in the art to adapt Gradon et al with the specified pressure and flow rate to further control the desired humidification.

***Response to Arguments***

6. Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

The applicant argues that the present invention uses the open-loop control system without a patient end sensor. Aside from the issue of what would define the patient end sensor, the applied prior art Gradon et al teaches that the conditions of the conduit heater is determined to further control the desired humidity. This control loop shows that Gardon et al also uses the open loop system as done in the present invention. Furthermore, the fact that the conduit heater is powered to produce the heat necessary to maintain the desired humidity level is an indication that temperature exists in the conduit heater and necessarily the resistance since without such resistance, the electric power cannot be produced.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sang Y Paik whose telephone number is 703-308-1147. The examiner can normally be reached on M-F (9:00-4:00) First Friday Off.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sang Y Paik
Primary Examiner
Art Unit 3742

syp